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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,508	08/09/2005	Hiroyuki Aburatani	392.1001	4237

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,508	ABURATANI ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 15-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8, 15-18 are examined in the instant application.

Withdrawn Rejection

The following rejections have been withdrawn: 1) Objection, and 2) 112, second paragraph, concerning the confusing language "having" followed by "consisting of", in view of the amendment.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The response asserts that the amendment of claim 3 obviates its rejection.

The response has been considered but is not found to be persuasive for the following reasons:

Rejection remains, because it not clear what constitutes a "normal control level". For example, the test sample is blood, serum or plasma from hepatic cancer patient, and the normal control level of GPC3 could be its level in any non-cancerous tissue, for example, bladder, lung or brain etc…, and not necessary in serum of non-cancerous subject.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 15-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons already of record in paper of 02/21/08.

The response asserts as follows:

The present invention is directed to a method for detecting (not diagnosing) the presence of cancer in a subject, regardless of the presence or absence of liver cirrhosis or melanoma in that subject. It is not necessary to distinguish between cancer and cirrhosis or melanoma. In other words, a subject who shows an increased level of GPC3 as detected by the invention may also have cirrhosis or melanoma, or may not. The specification, at the very least, establishes a predictive correlation between a greater level of soluble GPC3 in sera and the presence of in vivo tumor, as compared to normal control, and thus detection of cancer is established, as claimed.

Further, the claimed method of detecting cancer by determining increased levels of soluble GPC3, as compared to normal controls, has been demonstrated in human patients having hepatic cell cancer. The protocol and results of the experiments carried out in these human subjects is presented in Appendix A of Dr. Matsuura's expert declaration submitted under 37 CFR 1.132, wherein Dr. Matsuura confirms that over-expression of soluble GPC3 is frequently and predictably detected in human patients with hepatic cancer.

The submission of the Declaration by Dr. Matsuura is acknowledged.

The response has been considered but is not found to be persuasive for the following reasons:

Although, similar to non-cancerous liver tissue, the level of GPC3 mRNA is low in liver cirrohosis tissue (figure 3 in the instant specification), the level of soluble GPC3 protein is increased in serum of patients having liver cirrhosis, as taught by Hippo et al, of record Further, in the Declaration, patients with liver dysfunction are excluded from serum samples of hepatic cancer patients (p.6, paragraph under "Serum samples". Such exclusion is not found in the claimed method, or in the specification.

One cannot predict that an increase level of GPC3 protein in a serum test sample is indicative of hepatic cancer, in view that the level of soluble GPC3 protein is also increased in serum of patients having liver cirrhosis, as taught by Hippo et al, of record. In other words, the claimed method is non-specific. In view of such unpredictability, it would be undue experimentation for one to practice the claimed method.

Moreover, since it is not clear what constitutes a normal control level, one would not know how to practice the claimed method.

Further, it is noted that other than in blood, serum, or plasma, there is no indication that soluble GPC3 is found in liver cancer tissue.

Concerning the issue of "prediction" of detecting cancer, this limitation is not in the claims, nor in the originally elected invention. Further, the issue of whether it is necessary to distinguish between hepatic cancer and cirrhosis is not germane here, because it is the practical issue from the result of the claimed method. For example, the practical issue of treating patients having cirrhosis, but diagnosed as having hepatic cancer, and treated with cancer therapy.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
September 26, 2008

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643